

Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S.
Director of Professional Services
October 27, 2016



Goals

- Review recent changes to pharmacy rules;
- Review the most common Warning Notices Issued to Pharmacies;
- Review pharmacy related legislation passed by the 2015 Legislature; and
- Review some current issues facing the Board.



Board of Pharmacy Members

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Recently Adopted Rules



Grounds for Discipline

- Effective Date: December 6, 2015.
- It is a ground for discipline of a pharmacist or pharmacy technician if the individual exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.



Grounds for Discipline

- Effective Date: March 10, 2016.
- It is a ground for discipline of a pharmacy license if the owner, managing officer(s), or other pharmacy employee(s) exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.



Grounds for Discipline

- Effective mid September
- Implement provisions of SB 460
- It is a ground for discipline of a pharmacy license if the pharmacy waives, discounts, or reduces, or offers to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of:



Grounds for Discipline

- a legitimate, documented financial hardship of the patient; or
- evidence of a good faith effort to collect the copayment or deductible from the patient.



Pharmacist-in-Charge

- Effective Date: December 6, 2015.
- A pharmacist-in-charge (PIC) of a Class A Pharmacy may not also be the PIC of a:
 - Class B Pharmacy; or
 - Class C Pharmacy in a hospital with 101 beds or more.



Administration of Immunizations and Vaccines

- Effective Date: December 6, 2015.
- Before preparing an immunization/vaccine and between each patient contact:
 - Pharmacist must:
 - cleanse their hands with an alcohol-based waterless antiseptic hand rub; or
 - wash their hands with soap and water.
 - If gloves are worn, pharmacists must change gloves between patients.



Prescription Transfers

- Effective June 12, 2016.
- The transfer of prescriptions must be completed within four business hours of the request.



Pharmacists and Pharmacy Technicians



Pharmacy Technician's Continuing Education

- Effective Date: September 14, 2015. Amendments to §297.8 (Continuing Education) rules to:
 - Decrease the number of in-service hours from 10 to 5 hours;
 - Clarify the requirements for CE; and
 - Clarify the types of programs that count for continuing education.



Licensing Fee Changes

License	Renewal Fee Effective October 1, 2015	Change
Pharmacist	\$276	\$25 decrease
Pharmacies	\$452	\$80 decrease
Pharmacy Technicians	\$77	\$19 decrease
Pharmacy Technician Trainees	\$52	\$10 decrease



Conditions Receiving "Warning Notices" FY2015



Number of Inspections

Class	FY2015	% of FY2015 Inspections
Class A Pharmacies	2,275	76%
Class A-S	144	5%
Class B Pharmacies	5	<1%
Class C Pharmacies	268	9%
Class C-S	128	4%
Class D Pharmacies	95	3%
Class F Pharmacies	61	2%
Class G Pharmacies	15	<1%
Totals	2,991	100%

Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	992	77%
Class A-S	84	6%
Class B	2	<1%
Class C	80	6%
Class C-S	87	7%
Class D	31	2%
Class F	17	1%
Class G	0	N/A
Totals	1,293	100%

Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*
Records	731
Sterile Preparations	647
Pharmacy Technicians	564
Drug/Stock Environment	421
Prescriptions	335
Inventory	319
* One pharmacy may receive multiple Warning Notice violations.	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Records		731
Records Not Available	314	
Absence of R.Ph. Record	66	
Rx Not Separated	17	
Rx Records Not Numerical Order	25	
Improper Transfer of RX copies	3	
Invoices Not Separated/Retrievable	122	
Records for Non-Sterile Compounds	169	
No Written Information on RX	10	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Sterile Preparations		647
No/Incomplete QA/QC	99	
No/Incomplete P&P Manual	237	
No/Inadequate Preparation Area	165	
IV Preparation	131	
No DUR	13	
Cytotoxic/Bio Procedures	2	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Pharmacy Technicians		564
No/Incomplete Training	510	
No/Improper Supervision	19	
Improper Registration	29	
No Name Tags	6	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Drug Stock/Environment		421
Improper Environment	137	
Out-of-Date Drug Stock	158	
Security	65	
Unsanitary	32	
Improper Drug Storage	20	
Area for Non-Sterile Compounding	7	
Violation of Limited Formulary	2	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Prescriptions		335
Lack Proper Information	159	
Prescription Label Incorrect	136	
Official Rx Non-Compliance	40	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Inventory		319
No Annual Inventory	84	
No Change of Ownership Inventory	5	
No Change of PIC Inventory	35	
Incomplete Inventory	194	
Improper Drug Destruction	1	

Violations NOT Resulting in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.



Violations NOT Resulting in Warning Notices

- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



Violations NOT Resulting in Warning Notices

- Egregious Conditions
 - Dispensing CII's pursuant to prescriptions not issued on an Official Form;
 - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
 - Pharmacy closed and did not notify TSBP of closing;
 - Operating without a PIC for an extended period of time (i.e., 3 months or more).



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Violations NOT Resulting in Warning Notices

- Continuing threat – For example:
 - Impaired pharmacist on duty; or
 - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to “*cease and desist*” sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an Emergency Temporary Suspension Hearing.



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H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow a pharmacist to administer epinephrine, using an auto-injector, to a patient in an emergency situation.
 - Specify a pharmacist may not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.



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H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
 - Specify that a pharmacist who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.



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Bullard pharmacist saves patient's life thanks to new law

Published on Thursday, 17 March 2016 17:30 - Author: [Cynthia D. Baker, editor@texasboardofpharmacy.com](#)

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Pharmacist Cely Baker saved a woman's life by administering an EpiPen, a device which treats life-threatening allergic reactions. (Credit: A. Allen/Forbes Magazine)

Bullard pharmacist Cely Baker saved a woman's life, thanks to a new law enacted in Texas earlier this year.

A customer walked in the Brookshire's pharmacy in Bullard with her husband on March 4, visibly in need of medical attention. She asked for allergy medicine.

"It was pretty clear that she needed more than Benadryl, because her eyes were swollen shut, and she had trouble breathing," Ms. Baker said.

The Bullard native grabbed an EpiPen and injected the medicine into the patient's thigh. Ms. Baker said the patient felt better soon after and could breathe again. She monitored the woman for a while until the swelling had gone down, and she could breathe freely, as required. She then called 911, notified her physician and documented what happened.

Before, she would not have been able to legally administer the drug to a patient. In January, Texas legislators passed a law that allows a pharmacist to administer an epinephrine auto-injector to a patient in an emergency situation. It also provides liability protections for administering the drug.

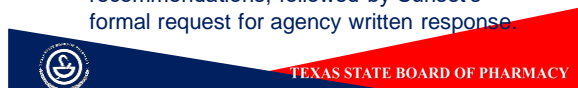
Sunset Review

- Texas Pharmacy Act, Sec. 551.005.
Application of Sunset Act.
 - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.



Sunset Review Time Line

- August 2015.
 - TSBP prepared a Self-Evaluation Report.
- October 2015 – March 2016.
 - Sunset staff reviewed the agency.
- Late March 2016.
 - Sunset's confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset's formal request for agency written response.



Sunset Review Time Line (cont.)

- April 2016.
 - Sunset staff report published.
- July 23, 2016.
 - Sunset Commission public hearing and made decisions on the review of the agency.
- January – May 2017.
 - 2017 Legislative Session – Sunset Bill introduced.



Sunset Report

- The Texas State Board of Pharmacy has established itself as a well-run agency capable of effectively responding to new regulatory issues and legislative mandates within its limited resources.
- Absent major problems with the board's basic duties, Sunset staff focused on the prescription drug abuse epidemic facing the country, which claimed 23,000 lives nationally in 2013 and was a constant backdrop to the review.



Sunset Report (cont.)

- Staff closely evaluated the board's new role over the Prescription Monitoring Program, the state's key tool for keeping track of the more than 11 million prescriptions distributed in Texas each year for highly addictive drugs such as Vicodin, Xanax, and OxyContin.



Sunset Decisions

Issue 1

- Beginning in 2018, require pharmacists to search the Prescription Monitoring Program database before dispensing certain controlled substances.
- Require pharmacists to enter dispensing information in the Prescription Monitoring Program database within one business day of dispensing controlled substances.



Sunset Decisions (cont.)

- Authorize the board to send push notifications and to set related thresholds.
- Direct the board to create delegate accounts for pharmacy technicians, work to integrate the program with pharmacy software systems, and make trend data on dispensing publicly available.



Sunset Decisions (cont.)

Issue 2

- Require the board to create a system of graduated penalties for late renewal of pharmacy technician registration.
- Authorize the board to deny renewal applications for licensees and registrants who are noncompliant with an existing board order.
- Direct the board to remove burdensome requirements that pharmacy licensure renewal forms be notarized.
- Direct the board to query a national disciplinary database before license renewal.



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Sunset Decisions (cont.)

Issue 3

- Continue the Texas State Board of Pharmacy for 12 years.
- The board should develop and implement a succession plan to prepare for impending retirements.



TEXAS STATE BOARD OF PHARMACY

S.B. 195 by Sen. Schwertner

- Passed during the 2015 Legislative Session;
- Moved the Prescription Monitoring Program from the Department of Public Safety (DPS) to the Board of Pharmacy; and
- Eliminated the Texas Controlled Substance Registration program.



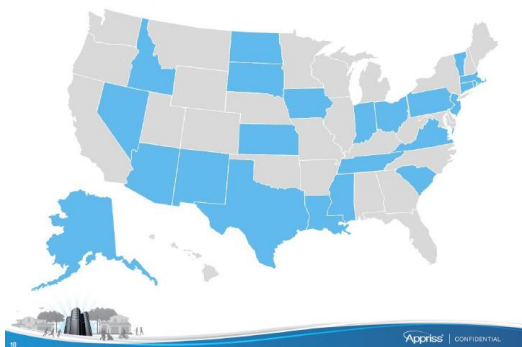
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Timeline for Transfer of the PMP Program

- **November 2015** – RFP for the new PMP issued by TSBP.
- **January 2016** – **Appriss selected as the vendor.**



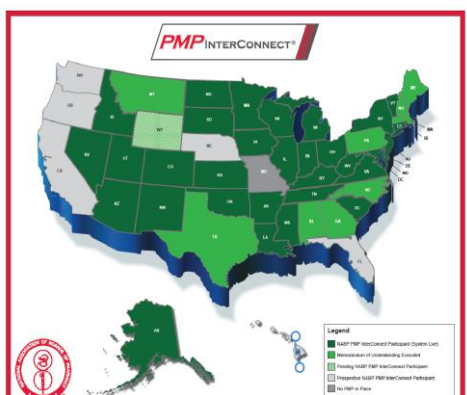
23 States Rely on Appriss' PMP Solution



PMP InterConnect: A Nationwide PMP Data Sharing Platform

- In 2011 Appriss launched PMP InterConnect to facilitate interoperability and interstate data sharing between state PMPs.
- Currently 32 states connected and climbing
- Features Include:
 - A "smart hub" routing methodology
 - A "rules engine" to enforce interstate data sharing permissions
- Currently processing > 1.8M requests per month and increasing month-over-month





Timeline for Transfer of the PMP Program

- February – May 2016 – System installation at TSBP.
- February 2016 – Board adopted new [Chapter 315](#) to implement PMP and provisions related to prescriptions in the Controlled Substances Act.
 - The rules became effective on [9/1/2016](#).
- May – August 2016 – Testing program.
- September 1, 2016 – NEW PMP is live.



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Texas Prescription Monitoring Program

The Texas Prescription Monitoring Program (PMP) collects and monitors prescription data for all Schedule II, III, IV and V controlled substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state. The PMP also provides a venue for monitoring patient prescription history for practitioners and the ordering of Schedule II Texas Official Prescription Forms. Click [here](#) for more information about the PMP.

[Prescription Monitoring Program FAQ's](#)

[YouTube Introduction Video](#)

VERIFICATIONS

[Verify a PMP Profile](#)

TEXAS PMP

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LOGIN

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AWARE/CLEARINGHOUSE

AWARE – User portal for prescription monitoring. Pharmacies and practitioners may use this site to access the information regarding the reporting and patient records of controlled substance prescriptions.

AWARE FAQ's

PMP Clearinghouse – Dispenser portal for reporting to the prescription monitoring program.

Clearinghouse FAQ's

Dispenser Data Submission Guide

Registration Manual

Quick Reference Guide - Making a Request in PMP AWARE



Texas Prescription Monitoring Program

Frequently Asked Questions

- Is TSBP going to renew my Controlled Substances Registration?**

No, a registration with the Federal Drug Enforcement Administration (DEA) and a license with a Texas Board is now required to handle controlled substances.

- Is the supervising physician's name required to be on an official prescription form for mid-level practitioners?**

Yes, the official prescription forms ordered by mid-level practitioners must include the supervising physician's name and DEA number.

CONTACT

[Contact Us](#)

[User Support Manual](#)

OFFICIAL PRESCRIPTION FORM ORDER

Official CII Prescription Forms – For more information regarding the ordering of official CII prescription pads.

[Ordering Official CII Prescription Forms](#)

[CII Prescription Forms FAQ's](#)

NEWS

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Frequently Accessed Information

- [Pharmacy Tools](#)
- [News](#)
- [Ask TSBP](#)
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IMPORTANT LINKS

Important links regarding controlled substances:

- [Texas Medical Board Guidelines for Pain Management \(Texas Administrative Code 170.3\)](#)
- [Certified Pain Management Clinics](#)
- [Legal Official Prescription Forms](#)
- [Electronic Prescriptions for Controlled Substances](#)
- [Bx Portal](#)
- [AWARE](#)
- [Information on Controlled Substance Prescriptions from Advanced Practice Registered Nurses and Physician Assistants](#)
- [Drug Disposal Information](#)
- [Corresponding Responsibility - A Shared Obligation](#)

If you have questions regarding the Texas Prescription Monitoring Program please contact us by e-Mail - tsbp@pharmacy.texas.gov

Phone - (512) 305-8059

PMP AWARxE

🌐 Login to website:

🌐 texas.pmpaware.net

The screenshot shows the login page for the Texas Prescription Monitoring Program (PMP AWARxE). At the top, there is a header with the Texas State Board of Pharmacy logo and the text "Texas Prescription Monitoring Program". Below the header, there is a "Log In" section with fields for "Email" and "Password". A "Reset Password" link is next to the password field. At the bottom of the login section, there are two buttons: "Login" and "Create an Account". A red arrow points to the "Create an Account" button.

For assistance using this application, please contact
844-477-4PMP (844-477-4767)
Austin, TX

Log In

Email

Password [Reset Password](#)

[Login](#) [Create an Account](#)

Users with existing accounts were transferred to the new system. Login using email and reset password. New users can create an account.

The screenshot shows the registration process page for the Texas Prescription Monitoring Program (PMP AWARxE). The page title is "Registration Process". Below the title, there is a section for "Create an Account" with fields for "Email", "Password", and "Confirm Password". A red arrow points to the "Create an Account" button at the bottom of the form.

Registration Process

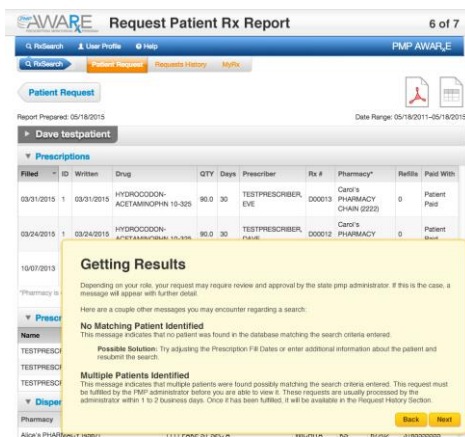
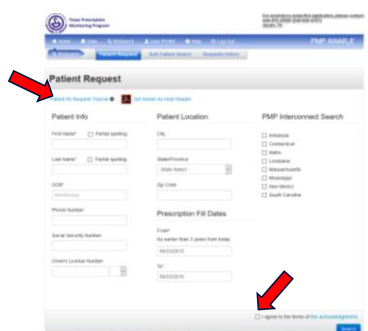
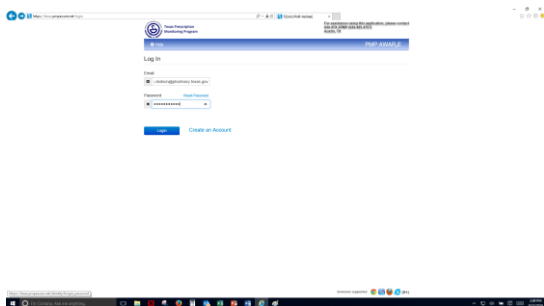
Create an Account

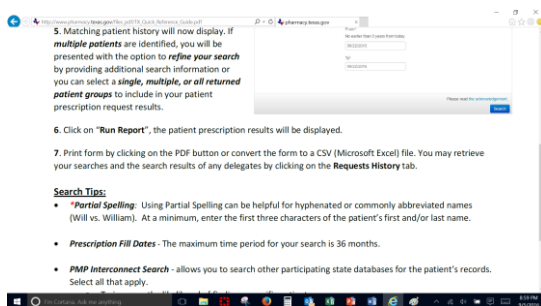
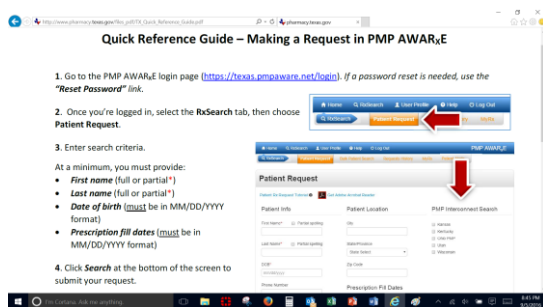
Email

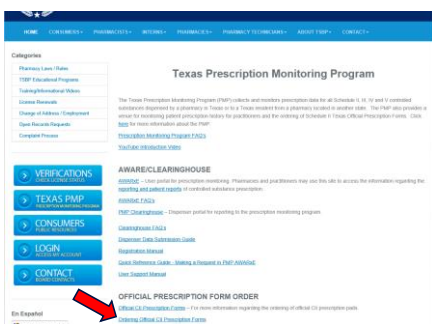
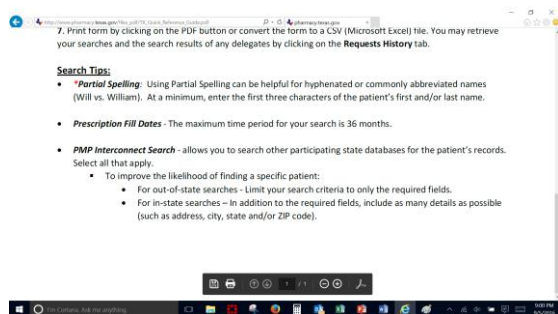
Password

Confirm Password

[Create an Account](#)









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Texas Prescription Monitoring Program

Official Prescription Form Orders

The ordering of Official Prescription Forms is available to the following link:
[Ordering Official Prescription Forms](#)

For information about ordering Official Prescription Forms, click on the link below:
[Prescription Monitoring Program FAQs](#)

Important Information Regarding Official Prescription:

- [Request Official Prescription Forms](#)
- [Electronic Prescriptions for Controlled Substances](#)


Electronic Copies of the Drug Laws and Rules for the Prescription Monitoring Program are available at the following links:
[Health and Safety Code, §§1](#)
[Texas Administrative Code](#)

Prescription forms, including triplicate forms, issued by DPS

Prescription forms, including triplicate forms, issued by DPS prior to 9/1/16 remain valid.

MUST BE FILLED WITHIN 7 DAYS ()		REV. 3/85
PATIENT OR LEGAL GUARDIAN NAME (PLEASE PRINT)		DATE ISSUED
PATIENT OR LEGAL GUARDIAN ADDRESS (PLEASE PRINT)		DATE
<input type="checkbox"/> SIMPLE PRESCRIPTION ONLY PRESCRIPTION INDICATE IF BRAND MEDICALLY NECESSARY		CITY STATE ZIP CODE
<input type="checkbox"/> L <input type="checkbox"/> R <input type="checkbox"/> BIL <input type="checkbox"/> N <input type="checkbox"/> OTH		
PHARMACY USE ONLY PRESCRIPTION INFORMATION PRESCRIPTION NUMBER 054 89464060 PRESCRIPTION NUMBER MSC 0439 P 1087 78773 PHONE ()		
PHARMACY ADDRESS CITY STATE ZIP CODE	DATE FILLED <input type="checkbox"/> CHECK IF EMERGENCY CONTAINMENT NUMBER 02347 17 133 25	PH. NUMBER

Still valid prescription forms!



Texas State Board of Pharmacy

Official Prescription Form Order

Welcome

Welcome to the Texas State Board of Pharmacy (TSBOP) Prescription Form Order System.

To access this system, you must first register with the Texas State Board of Pharmacy.

Click here to view a list of frequently asked questions.

What you will need:

- A valid DEA number, NPI, and DPT Code
- A business address (including Office Phone Number)
- Valid email (Gmail, Hotmail, etc.)
- Business Name, Address, and/or Electronic Data Interchange


This online service is provided by Texas.gov, the official website of Texas. The price of this service includes TexasRx that supports the ongoing operations and improvements of Texas.gov which is provided by either party in partnership with the State.

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Help

For questions about our service with the Texas State Board of Pharmacy, please contact 817-255-0800 or email us at help@texas.gov

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 Texas State Board of Pharmacy
 January 12, 2011

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[TexasRx Events](#)
[TexasRx Press](#)
[TexasRx Blog](#)
[TexasRx RSS](#)
[TexasRx Twitter](#)
[TexasRx Facebook](#)
[TexasRx LinkedIn](#)
[TexasRx YouTube](#)
[TexasRx Instagram](#)
[TexasRx Snapchat](#)
[TexasRx TikTok](#)
[TexasRx Twitch](#)
[TexasRx Discord](#)
[TexasRx Slack](#)
[TexasRx Telegram](#)
[TexasRx WhatsApp](#)
[TexasRx Messenger](#)
[TexasRx Email](#)
[TexasRx Phone](#)
[TexasRx Fax](#)
[TexasRx Mail](#)
[TexasRx Courier](#)
[TexasRx Express](#)
[TexasRx Overnight](#)
[TexasRx Priority](#)
[TexasRx Standard](#)
[TexasRx Economy](#)
[TexasRx Budget](#)
[TexasRx Free](#)
[TexasRx Low Cost](#)
[TexasRx Discount](#)
[TexasRx Sale](#)
[TexasRx Clearance](#)
[TexasRx Liquidation](#)
[TexasRx Auction](#)
[TexasRx Marketplace](#)
[TexasRx Store](#)
[TexasRx Shop](#)
[TexasRx Outlet](#)
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FIRST M LAST MD
123 SAMPLE ST
AUSTIN TX 78701
Phone # (512) 555-5555

CEAB M2400090
CTRL# 15243001189

Name _____
Address _____
AOC on DQB _____ Date _____

Practitioner Signature - Indicate if "Shared Medical Necessity"

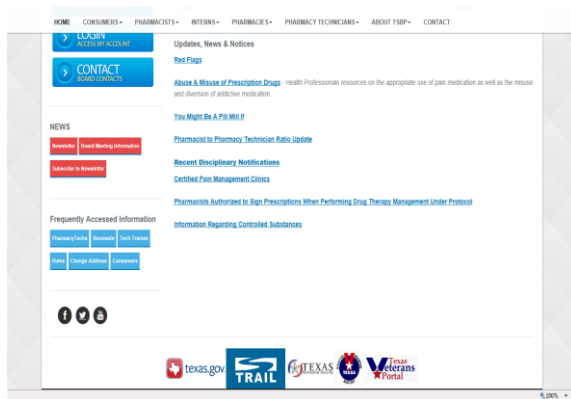
Pharmacist Signature _____
Rx Number _____ Date Filled _____

SECURITY FEATURES ON BACK

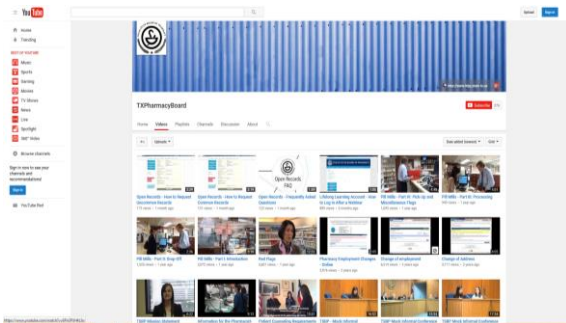


TSBP Website
www.pharmacy.texas.gov









Thank You!

